EXACT COPY
INITIALS JLS DATE 6-27-16

AMENDMENT TO GLP TEST PROTOCOL

ACCURATUS —LAB SERVICES— THE ANTIMICROBIAL AUTHORITY

Amendment No.:	1
Effective Date:	April 28, 2016
Sponsor:	CID LINES nv Waterpoortstraat 2 Ieper 8900 Belgium
Test Facility:	Accuratus Lab Services 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121
Protocol Title:	AOAC Use-Dilution Method
Protocol Number:	SRC46121515.UD.1
Project Number:	A20669

Modifications to Protocol:

Per Sponsor request, additional testing will be added to this protocol. Lot S514701 will also be tested against *Staphylococcus aureus* at a 9 minute 45 second exposure time.

Changes to the protocol are acceptable as noted.

Study Director — Date: 4/28/16

Sponsor Representative — Date: 4-29-16

(For Laboratory Use Only) CWC 4/8/16
Accuratus Lab Services Project # A20669
Test Substance Tracking #:
T5010416 · SRC46 4/5/16 PROTOCOL

ACCURATUS LAB SERVICES

AOAC Use-Dilution Method

Test Organism(s):

Staphylococcus aureus (ATCC 6538)
Salmonella enterica (ATCC 10708)

PROTOCOL NUMBER

SRC46121515.UD.1

PREPARED FOR/SPONSOR

CID LINES nv
Waterpoortstraat 2
Ieper 8900
Belgium

SPONSOR REPRESENTATIVE

Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street
Columbia City, IN 46725

PREPARED BY/TESTING FACILITY

Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

DATE

December 15, 2015

EXACT COPY
INITIALS JLS DATE 6-27-16

AOAC Use-Dilution Method

PURPOSE
The purpose of this study is to determine the effectiveness of the Sponsor's product as a disinfectant for hard surfaces following the AOAC Use-Dilution Method. This method is in compliance with the requirements of and may be submitted to, one or more of the following agencies as indicated by the Sponsor: U.S. Environmental Protection Agency (EPA), Health Canada and Australian Therapeutic Goods Administration (TGA).

TEST SUBSTANCE CHARACTERIZATION
According to 40 CFR, Part 160, Subpart F [160.105] test substance characterization as to identity, strength, purity, solubility and composition, as applicable, shall be documented before its use in this study. The stability of the test substance shall be determined prior to or concurrently with this study. Pertinent information, which may affect the outcome of this study, shall be communicated in writing to the Study Director upon sample submission to Accuratus Lab Services. Accuratus Lab Services will append Sponsor-provided Certificates of Analysis (C of A) to this study report, if requested and supplied. Characterization and stability studies not performed following GLP regulations will be noted in the Good Laboratory Practice compliance statement.

SCHEDULING AND DISCLAIMER OF WARRANTY
Experimental start dates are generally scheduled on a first-come/first-serve basis once Accuratus Lab Services receives the Sponsor approved/completed protocol, signed fee schedule and corresponding test substance(s). Based on all required materials being received at this time, the proposed experimental start date is January 4, 2016. Verbal results may be given upon completion of the study with a written report to follow on the proposed completion date of February 1, 2016. To expedite scheduling, please be sure all required paperwork and test substance documentation is complete/accurate upon arrival at Accuratus Lab Services.

If a test must be repeated, or a portion of it, due to failure by Accuratus Lab Services to adhere to specified procedures, it will be repeated free of charge. If a test must be repeated, or a portion of it, due to failure of internal controls, it will be repeated free of charge. "Methods Development" fees shall be assessed, however, if the test substance and/or test system require modifications due to complexity and difficulty of testing. If the Sponsor requests a repeat test, they will be charged for an additional test. Neither the name of Accuratus Lab Services nor any of its employees are to be used in advertising or other promotion without written consent from Accuratus Lab Services.

The Sponsor is responsible for any rejection of the final report by the regulating agencies concerning report format, pagination, etc. To prevent rejection, Sponsor should carefully review the Accuratus Lab Services final report and notify Accuratus Lab Services of any perceived deficiencies in these areas before submission of the report to the regulatory agency. Accuratus Lab Services will make reasonable changes deemed necessary by the Sponsor, without altering the technical data.

JUSTIFICATION FOR SELECTION OF THE TEST SYSTEM
Regulatory Agencies require that a specific organism claim for a test substance intended for use on hard surfaces be supported by appropriate scientific data demonstrating the efficacy of the test substance against the claimed organism. This is accomplished in the laboratory by treating the target organism with the test substance under conditions which simulate as closely as possible the actual conditions under which the test substance is designed to be used. For products intended for use on hard surfaces (dry, inanimate environmental surfaces), a carrier method is used in the generation of the supporting data. The experimental design in this protocol meets these requirements.

TEST PRINCIPLE

A film of organism cells dried on a surface of stainless steel carriers is exposed to the test substance for a specified exposure time. After exposure, the carriers are transferred to vessels containing neutralizing subculture media and assayed for survivors. Appropriate culture purity, sterility, viability, carrier population and neutralization confirmation controls are performed. The current revision of Standard Operating Procedure CGT-0041 reflects the methods which shall be used in this study.

TEST METHOD

Table 1.

Test Organism	Designation #	Growth Medium	Incubation Parameters
Staphylococcus aureus	6538	Synthetic Broth	35-37°C, aerobic
Salmonella enterica	10708	Synthetic Broth	35-37°C, aerobic

The test organism(s) to be used in this study was/were obtained from the American Type Culture Collection (ATCC), Manassas, VA.

Recovery Agar Medium: Tryptic Soy Agar + 5% Sheep's Blood

Carriers

Carriers will be screened according to AOAC Official Method of Analysis and any carrier positive for growth will be discarded. Only penicylinders showing no growth may be used. Stainless steel penicylinders will be pre-soaked overnight in 1N NaOH, washed in water until neutral and autoclaved in deionized water. Carriers shall be used within three months of sterilization.

Preparation of Test Organism

Transfer 10 µL of a thawed, vortex mixed, cryovial of stock organism broth culture to an initial 10 mL tube of growth medium. For organisms not defined in the AOAC Use Dilution method, a loopful of stock slant culture may be used to inoculate the initial 10 mL tube of growth medium.

Mix and incubate the initial culture for 24±2 hours at the incubation conditions above. Following incubation, transfer 10 µL of culture to sufficient 20 x 150 mm Morton closure tubes containing 10 mL of culture medium (daily transfer #1). One daily transfer is required but up to four additional daily transfers may be prepared. Incubate the final test culture for 48-54 hours at the incubation conditions above.

The test culture will be vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture will be removed, leaving behind any clumps or debris and will be pooled in a sterile vessel and mixed.

The culture may be diluted or centrifuge-concentrated. Applicable culture dilutions shall be performed using sterile growth medium. An organic soil load will be added to the test culture per Sponsor's request. The final test culture will be mixed thoroughly prior to use.

Contamination of Carriers
The culture will be transferred to the penicylinders (after siphoning off the water) and the carriers will be immersed for 15±2 minutes in a prepared suspension at a ratio of one carrier per one mL of culture to completely cover the carriers. A maximum of 100 carriers will be inoculated per vessel and each vessel inoculated may be considered a part of one total inoculation run per organism. The inoculated carriers will be transferred to sterile Petri dishes matted with filter paper after tapping the carrier against the side of the container to remove excess inoculum. No more than twelve carriers will be placed in each Petri dish. The carriers will be dried for 40±2 minutes. *NOTE: Organisms not specifically mentioned in the AOAC methodology may require modified drying conditions for the purpose of obtaining maximum survival following drying. The actual drying conditions will be clearly documented.* Carriers will be used in the test procedure within 2 hours of drying. Carriers that touch during drying or have fallen over will not be used in the test.

Drying Conditions: 35-37°C.

Preparation of Test Substance
The test substance(s) to be assayed will be used as directed by the Sponsor. If a dilution of the test substance is requested by the Sponsor, the diluted test substance(s) shall be used within three hours of preparation. For products requiring dilution, use ≥1.0 mL or ≥1.0 g of test substance and volumetric glassware when preparing the dilution unless otherwise specified by the Sponsor. Ten (10) mL of the test substance at its use-dilution will be aliquotted into the required number of sterile 25 x 150 mm or 25 x 100 mm tubes. The tubes will be placed into a waterbath at the specified exposure temperature, and allowed to equilibrate for ≥10 minutes prior to testing.

Exposure Conditions
Each contaminated and dried carrier will be placed into a separate tube containing 10 mL of the test substance at its use-dilution for the desired exposure time and temperature. Immediately after placing each test carrier in the test tube, swirl the tube using approximately 2–3 gentle rotations to release any air bubbles trapped in or on the carrier. Care will be taken to avoid touching the sides of the tubes which may compromise exposure. The carrier will be placed into the test substance within ±5 seconds of the exposure time for exposure times above 1 minute following a calibrated timer. The carrier will be placed into the test substance within ±3 seconds of the exposure time for exposure times of ≤1 minute. If the exposure conditions are compromised in any way for a given carrier, a new carrier may be treated in its place. If this cannot be done, the carrier will be marked and the compromised carrier will be identified in the raw data. If a marked carrier demonstrates a positive result, the carrier set may be invalidated and repeated by Sponsor request.

Test System Recovery
Following the Sponsor specified exposure time, each medicated carrier will be transferred by wire hook at staggered intervals to 10 mL of primary neutralizing subculture medium and each tube will be shaken thoroughly. To accomplish this, the carrier is removed from the disinfectant tube with a sterile hook, tapped against the interior sides of the tube to remove the excess disinfectant, avoiding the upper one-third of the tube, and transferred into the subculture tube. Care will be taken to avoid excessive contact to the interior sides of the subculture tubes during transfer. If secondary neutralization is requested by the Sponsor or deemed necessary due to test substance active and/or concentration, carriers will be transferred into individual secondary subculture tubes containing 10 mL of neutralizing broth beginning approximately 25-60 minutes after subculture of the carrier into the primary neutralizing subculture medium. Shake each tube thoroughly. If neutralization is a concern, 20 mL of subculture medium may be used.

Incubation and Observation
All subcultures are incubated under the conditions listed in table 1 for 48±2 hours.

Following incubation, the subcultures will be visually examined for growth. If necessary, the subcultures may be placed at 2-8°C for up to three days prior to examination.

Representative subculture tubes showing growth will be subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. If growth cannot be determined visually, appropriate test and/or control subcultures may be streaked to agar to determine the presence or absence of growth.

STUDY CONTROLS

Purity Control
A "streak plate for isolation" will be performed on the organism culture and following incubation examined in order to confirm the presence of a pure culture. The acceptance criterion for this study control is a pure culture demonstrating colony morphology typical of the test organism.

Organic Soil Sterility Control
Prior to or concurrent with testing and if applicable, the serum used for the organic soil load will be cultured, incubated, and visually examined for lack of growth. The acceptance criterion for this study control is lack of growth.

Carrier Sterility Control
Prior to or concurrent with testing, a representative uninoculated carrier will be added to an appropriate subculture medium. The subculture medium containing the carrier will be incubated and examined for growth. The acceptance criterion for this study control is lack of growth.

Neutralizing Subculture Medium Sterility Control
Prior to or concurrent with testing, a representative sample of uninoculated neutralizing subculture medium will be incubated and visually examined. The acceptance criterion for this study control is lack of growth.

Viability Control
One representative inoculated carrier will be added to a vessel containing each type of subculture medium. If secondary subcultures are performed using a different media type, one carrier will be placed in the primary subculture medium and one carrier will be placed in the secondary subculture medium. The vessels containing each carrier will be incubated and visually examined for growth. The acceptance criterion for this study control is growth in the subculture media.

Neutralization Confirmation Control
Prior to testing or concurrent with testing, the neutralization of the test substance will be confirmed by exposing at least one sterile carrier to the test substance and transferring the carrier to primary subcultures containing 10-20 mL of neutralizing subculture medium as in the test. If performed in the test procedure, each carrier will then be transferred from primary subcultures into individual secondary subcultures beginning approximately 25-60 minutes following the primary transfer. The subcultures (primary and secondary as applicable) will be inoculated with a target of 10-100 colony forming units (CFU) of each test organism, incubated under test conditions and visually examined for the presence of growth. This control will be performed with multiple replicates using different dilutions of the test organism. A standardized spread plate procedure will be run concurrently in order to enumerate the number of CFU actually added per tube. NOTE: Only the most concentrated test substance dilution and/or shortest exposure time needs to be evaluated in this control.

The acceptance criterion for this study control is growth in the final subculture broth, minimally, following inoculation with ≤100 CFU per tube. If all the organism dilution(s) used in this control fail to provide adequate numbers (10-100 CFU) which coincides in a failure to meet the acceptance criterion for this study control, the control may be repeated in its entirety.

Carrier Population Control
Two sets of three inoculated carriers (one set prior to testing and one set following treatment) for each organism carrier set will be assayed. Each inoculated carrier will be individually subcultured into a tube containing 10 mL of neutralizing subculture medium and sonicated for 1 minute±5 seconds. Tubes will be contained in a beaker with water suspended in the ultrasonic cleaner such that all fluids will be level. Following sonication, the contents of the three subcultured carriers will be pooled (30 mL) and briefly vortex mixed. Appropriate serial ten-fold dilutions will be prepared and the duplicate 0.1 mL aliquots spread plated on agar plate medium, and incubated. If serial dilutions are not performed and plated immediately following sonication, the vessels may be refrigerated at 2-8°C for up to 2 hours prior to dilution. Following incubation, the resulting colonies will be enumerated. The individual CFU per carrier set results will be calculated, and the Log_{10} value of each carrier set determined. The average Log_{10} value per organism will be calculated. For *Staphylococcus aureus*, the acceptance criterion for this study control is a minimum average Log_{10} value of 6.0. For *Salmonella enterica*, the acceptance criterion for this study control is a minimum average Log_{10} value of 5.0.

PROCEDURE FOR IDENTIFICATION OF THE TEST SYSTEM

Accuratus Lab Services maintains Standard Operating Procedures (SOPs) relative to efficacy testing studies. Efficacy testing is performed in strict adherence to these SOPs which have been constructed to cover all aspects of the work including, but not limited to, receipt, log-in, and tracking of biological reagents including test organism strains for purposes of identification, receipt and use of chemical reagents. These procedures are designed to document each step of efficacy testing studies. Appropriate references to medium, batch number, etc. are documented in the raw data collected during the course of each study.

Additionally, each efficacy test is assigned a unique Project Number when the protocol for the study is initiated by the Study Director. This number is used for identification of the test subcultures, etc. during the course of the test. Test subcultures are also labeled with reference to the test organism, experimental start date, and test product. Microscopic and/or macroscopic evaluations of positive subcultures are performed in order to confirm the identity of the test organism. These measures are designed to document the identity of the test system.

METHOD FOR CONTROL OF BIAS: NA

STUDY ACCEPTANCE CRITERIA

Test Substance Performance Criteria

For *Staphylococcus aureus*, the efficacy performance requirements for label claims state that the test substance must kill the microorganism on 57 out of the 60 inoculated carriers.

For *Salmonella enterica*, the efficacy performance requirements for label claims state that the test substance must kill the microorganism on 59 out of the 60 inoculated carriers.

Control Acceptance Criteria

The study controls must perform according to the criteria detailed in the study controls description section. If any control acceptance criteria are not met, the test may be repeated under the current protocol number. If the population control exceeds an average $\log_{10}$ value of 7.0 for *Staphylococcus aureus* or 6.0 for *Salmonella enterica*, and the test substance does not meet the performance criteria, the Sponsor may invalidate the study and repeat testing.

Any positive test carriers confirmed as a contaminant will be reported. Any test carrier set that demonstrates a number of contaminated tubes that contributes to results that exceed the product performance/success criteria may be invalidated per Sponsor's request and may be re-tested. For sixty carrier studies, contamination exceeding one tube per carrier set may warrant invalidation and repeat testing by Sponsor's request.

If any portion of the protocol is executed incorrectly warranting repeat testing, the test may be repeated under the current protocol number. If the population control fails to meet the minimum requirement or if the neutralization control acceptance criteria is not met and the study fails to meet the efficacy requirements, repeat testing is not required.

REPORT

The report will include, but not be limited to, identification of the sample, date received, initiation and completion dates, identification of the organism strains used, description of media and reagents, description of the methods employed, tabulated results and conclusion as it relates to the purpose of the test, and all other items required by 40 CFR Part 160.185.

PROTOCOL CHANGES

If it becomes necessary to make changes in the approved protocol, the revision and reasons for changes will be documented, reported to the Sponsor and will become a part of the permanent file for that study. Similarly, the Sponsor will be notified as soon as possible whenever an event occurs that may have an effect on the validity of the study.

Standard operating procedures used in this study will be the correct effective revision at the time of the work. Any minor changes to SOPs (for this study) or methods used will be documented in the raw data and approved by the Study Director.

TEST SUBSTANCE RETENTION

It is the responsibility of the Sponsor to retain a sample of the test substance. All unused test substance will be discarded following study completion unless otherwise indicated by Sponsor.

RECORD RETENTION

Study Specific Documents

All of the original raw data developed exclusively for this study shall be archived at Accuratus Lab Services for a minimum of five years for GLP studies or a minimum of six months for all other studies following the study completion date. After this time, the Sponsor (or the Sponsor Representative, if applicable) will be contacted to determine the final disposition. These original data include, but are not limited to, the following:

1. All handwritten raw data for control and test substances including, but not limited to notebooks, data forms and calculations.
2. Any protocol amendments/deviation notifications.
3. All measured data used in formulating the final report.
4. Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
5. Original signed protocol.
6. Certified copy of final study report.
7. Study-specific SOP deviations made during the study.

Facility Specific Documents

The following records shall also be archived at Accuratus Lab Services. These documents include, but are not limited to, the following:

1. SOPs which pertain to the study conducted.
2. Non study-specific SOP deviations made during the course of this study which may affect the results obtained during this study.
3. Methods which were used or referenced in the study conducted.
4. QA reports for each QA inspection with comments.
5. Facility Records: Temperature Logs (ambient, incubator, etc.), Instrument Logs, Calibration and Maintenance Records.
6. Current curriculum vitae, training records, and job descriptions for all personnel involved in the study.

REFERENCES

1. Association of Official Analytical Chemists (AOAC) Official Method 964.02, Testing Disinfectants against *Pseudomonas aeruginosa* - Use-Dilution Method. In Official Methods of Analysis of the AOAC, 2013 Edition.
2. Association of Official Analytical Chemists (AOAC) Official Method 955.15, Testing Disinfectants against *Staphylococcus aureus* - Use-Dilution Method. In Official Methods of Analysis of the AOAC, 2013 Edition.
3. Association of Official Analytical Chemists (AOAC) Official Method 955.14, Testing Disinfectants against *Salmonella enterica*- Use-Dilution Method. In Official Methods of Analysis of the AOAC, 2013 Edition.
4. Association of Official Analytical Chemists (AOAC) Official Method 960.09, Germicidal and Detergent Sanitizing Action of Disinfectants Method [Preparation of Synthetic Hard Water]. In Official Methods of Analysis of the AOAC, 2013 Edition.
5. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Uses of Antimicrobial Agents, September 4, 2012.
6. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2200: Disinfectants for Use on Hard Surfaces- Efficacy Data Recommendations, September 4, 2012.
7. Health Canada, January, 2014. Guidance Document – Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs.
8. Health Canada, January, 2014. Guidance Document - Disinfectant Drugs.
9. Australian Therapeutic Goods Administration (TGA), February 1998. Guidelines for the Evaluation of Sterilants and Disinfectants.
10. Australian Therapeutic Goods Administration (TGA), February 1998. Therapeutic Goods Order No. 54 Standard for Disinfectants and Sterilants.
11. Australian Therapeutic Goods Administration (TGA), March 1997. Therapeutic Goods Order No. 54A Amendment to the Standard for Disinfectants and Sterilants (TGO 54).

DATA ANALYSIS

Calculations

Determine the CFU/Carrier set in the Carrier Population Control using all average counts between 0-300 CFU as follows:

$$\text{CFU/carrier} = \frac{[(\text{avg. CFU for } 10^{-x}) + (\text{avg. CFU for } 10^{-y}) + (\text{avg. CFU for } 10^{-z})] \times (\text{Volume of neutralizer})}{[10^{-x} + 10^{-y} + 10^{-z}] \times (\text{Volume plated}) \times (\#\text{ of carriers per set})}$$

where 10^{-x}, 10^{-y}, and 10^{-z} are example dilutions that may be used.

$$\text{Average } \text{Log}_{10} \text{ Carrier Population Control} = \frac{\text{Log}_{10}X_1 + \text{Log}_{10}X_2 + \ldots \text{Log}_{10}X_N}{N}$$

Where: X equals CFU/carrier set
N equals number of control carrier sets

Statistical Analysis

None used.

STUDY INFORMATION

(All blank sections are completed by the Sponsor or Sponsor Representative as linked to their signature, unless otherwise noted.)

Test Substance (Name & Batch Numbers) exactly as it should appear on final report:

Test Date #1: Virocid, Lot S514701
Test Date #2: Virocid, Lot S514702
Test Date #3: Virocid, Lot S514703

Testing at the lower certified limit (LCL) is required for registration, no aged batch is necessary.

Product Description:

- ☑ Quaternary ammonia
- ☐ Iodophor
- ☐ Sodium hypochlorite
- ☐ Peracetic acid
- ☐ Peroxide
- ☑ Other Glutaraldehyde

Approximate Test Substance Active Concentration (upon submission to Accuratus Lab Services):

<2.1.4% quat., <9.4% glut.

(This value is used for neutralization planning only. This value is not intended to represent characterization values.)

Neutralization/Subculture Broth: See A20405 for neutralization technique.

(NOTE: All broth must also serve as an appropriate growth medium for the test organism)

☑ Accuratus Lab Services' Discretion. By checking, the Sponsor authorizes Accuratus Lab Services, at their discretion, to perform neutralization confirmation assays at the Sponsor's expense prior to testing to determine the most appropriate neutralizer. (See Fee Schedule).

Storage Conditions:

- ☑ Room Temperature
- ☐ 2-8°C
- ☐ Other:

Hazards:

- ☐ None known: Use Standard Precautions
- ☑ Material Safety Data Sheet, Attached for each product
- ☐ As Follows:

Product Preparation

- ☐ No dilution required, Use as received (RTU)
- ☑ *Dilution(s) to be tested:

1:170 defined as 1 part + 169 parts
(example: 1 oz/gallon) (amount of test substance) (amount of diluent)

- ☐ Deionized Water (Filter or Autoclave Sterilized)
- ☐ Tap Water (Filter or Autoclave Sterilized) - All tap water is softened; the water hardness for the batch of tap water used will be determined and reported.
- ☑ AOAC Synthetic Hard Water: 400 PPM
- ☐ Other

Note: An equivalent dilution may be made unless otherwise requested by the Sponsor.

Test Organism(s): ☑ *Staphylococcus aureus* (ATCC 6538)
☑ *Salmonella enterica* (ATCC 10708) – *all batches may be tested on one test date*

Carrier Number: 60 per batch

Exposure Time: 9.5 minutes **Exposure Temperature:** 20 ± 1 °C

Organic Soil Load:

- ☐ Minimum 5% Organic Soil Load (Fetal Bovine Serum)
- ☑ No Organic Soil Load Required
- ☐ Other:

TEST SUBSTANCE SHIPMENT STATUS

(This section is for informational purposes only.)

☑ Test Substance is already present at Accuratus Lab Services.

☐ Test Substance has been or will be shipped to Accuratus Lab Services.
Date of expected receipt at Accuratus Lab Services: _____

☐ Test Substance to be hand-delivered (must arrive by noon at least one day prior to testing or other arrangements made with the Study director).

COMPLIANCE

Study to be performed under EPA Good Laboratory Practice regulations (40 CFR Part 160) in accordance to standard operating procedures.

☑ Yes

☐ No (Non-GLP or Development Study)

REGULATORY AGENCY(S) THAT MAY REVIEW DATA

☑ U.S. EPA

☐ Health Canada

☐ Therapeutic Goods Administration (Australian TGA)

PROTOCOL MODIFICATIONS

☐ Approved without modification

☑ Approved with modification

The subculture broths will not be refrigerated after incubation. A draft report will be provided for review prior to finalization.

PROTOCOL ATTACHMENTS

Supplemental Information Form Attached - ☐ Yes ☑ No

TEST SUBSTANCE CHARACTERIZATION & STABILITY TESTING
[Verification required per 40 CFR Part 160 Subpart B (160.31(d))]

❑ Characterization/Stability testing is not required (For Non-GLP or Development testing only)

OR

Physical and Chemical Characterization (identity, purity, strength, solubility, as applicable) of the test lots

☑ **Physical & Chemical Characterization has been or will be completed prior to efficacy testing.**

GLP compliance status of physical & chemical characterization testing:
☑ Testing was or will be performed following 40 CFR Part 160 GLP regulations
❑ Characterization has not been or will not be performed following GLP regulations

Check and complete the following that apply:
☑ A Certificate of Analysis (C of A) may be provided for each lot of test substance. If provided, the C of A will be appended to the report.
❑ Testing has been or will be conducted at Accuratus Lab Services under protocol or study #:

_____

❑ Test has been or will be conducted by another facility under protocol or study #:

_____

❑ **Physical & Chemical Characterization was not or will not be performed prior to efficacy testing.**

Stability Testing of the formulation

☑ **Stability testing has been or will be completed prior to or concurrent with efficacy testing.**

GLP compliance status of stability testing:
(GLP compliance is required by 40 CFR Part 160)
☑ Testing was or will be performed following 40 CFR Part 160 GLP regulations
❑ Stability testing has not been or will not be performed following GLP regulations

Check and complete the following that apply:
☑ Testing has been or will be conducted at Accuratus Lab Services under protocol or study #:
A20171
❑ Test has been or will be conducted by another facility under protocol or study #:

_____

❑ **Stability testing was not or will not be performed prior to or concurrent with efficacy testing.**

If test substance characterization or stability testing information is not provided or is not performed following GLP regulations, this will be indicated in the GLP compliance statement of the final report.

APPROVAL SIGNATURES

SPONSOR:

NAME: Ms. Rhonda Jones TITLE: Agent

SIGNATURE: [signature] DATE: 4-4-16

PHONE: (260) 244 - 6270 FAX: (260) 244 – 6273 EMAIL: rjones@srcconsultants.com

For confidentiality purposes, study information will be released only to the sponsor/representative signing the protocol (above) unless other individuals are specifically authorized in writing to receive study information.

Other individuals authorized to receive information regarding this study: ☐ See Attached

Delphine Scopinski, Helene Charier, SRC Staff

Accuratus Lab Services:

NAME: Carrie K. Bauer
Study Director

SIGNATURE: [signature] DATE: 4/5/16
Study Director